DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on *11/23/2010* has been entered.

Applicant's response filed on *11/23/2010* in response to office action mailed on 05/12/2010 has been acknowledged.

Claims 1, 5, 7, 12-16, 18 and 19 are amended.

Claims 2-4, 11, 17 and 20-47 are canceled.

Claims 1, 5-10, 12-16, 18, and 19 are pending and presently under examination.

Applicants are required to follow Amendment Practice under revised 37 CFR §1.121. The fax phone numbers for the organization where this application or proceeding is assigned is ***571-273-8300.***

Applicants arguments in the response filed on *11/23/2010* are fully considered while writing this action.

Withdrawn: Claims 1-19 and 21 rejection under 102(b) as being anticipated by Hwang et al., (1999, Current Opinion in Molecular Therapeutics 1:471-479; art of record) for the reasons of record as set forth in the office action mailed on 05/12/2010 is withdrawn in view of Applicants amendments and cancellations to claims and further in view of revised rejections below.

Withdrawn: Claims 1, 3-6, 11-17, 19 and 21 rejection under 102(e) as being anticipated by McNeel et al., (US2004/01428290 A1; art of record) for the reasons of record as set forth in the office action mailed on 05/12/2010 is withdrawn in view of Applicants amendments and cancellations to claims and further in view of revised rejections below.

Withdrawn: Claims 1-8, 11-19 and 21 rejection under 35 USC 103 (a) as being unpatentable over McNeel et al., (US200401428290 A1; art of record) in view of Schlom et al., (WO 01/95919; art of record) for the reasons of record as set forth in the office action mailed on 05/12/2010 is withdrawn in view of Applicants amendments and cancellations to claims and further in view of revised rejections below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 5-10, 12-16, 18, and 19 are rejected under 35 USC 103 (a) as being unpatentable over Leong et al (1994, J. Virol. 68:8125-8130) in view of McNeel et al., (US200401428290 A1; art of record) and Hwang et al., (1999, Current Opinion in Molecular Therapeutics 1:471-479; art of record).

The above claims are drawn to a genetic vaccine construct comprising a fowlpox virus vector that encodes and expresses in a subject a xenogenic prostate specific polypeptide or a derivative or an analogue thereof and a sequence of nucleotides encoding an immune-stimulatory polypeptide. In further limitations PAP is of a rodent, rat. In still further limitations the immune-stimulatory peptide is a cytokine drawn a hybridization probe for detecting said constructs.

Leong teaches a genetic vaccine vector for delivering heterologous antigen wherein the vector is a fowlpox virus and the vector further comprises nucleotide sequence of encoding an immune-stimulatory polypeptide such as IL-6, IFN-gamma (entire article; abstract; p.8126, Fig.1-2; Tables 1-4). Leong teaches that a fowlpox virus vectors encoding cytokines represent a safe and effective vaccine strategy which may be used selectively manipulate the immune response (Abstract; p.8129). Leong however, does not teach that the heterologous antigen is a prostatic acid phosphatase).

Regarding claims limitations of xenogenic antigen being PAP McNeel teaches vaccine construct comprising a poxvirus vector and encoding and expressing a xenogenic

prostrate specific polypeptide, specifically prostatic acid phosphatase (human), and administering to a rat (see entire article; abstract; p.10 col.2 paragraphs 0087-0091). McNeel further teaches using fowlpox virus vector expressing the same antigenic polypeptide (PAP) as a "boost" in the prime boost protocols (p.6, paragraph 0046). McNeel further teaches generating antigen specific CTL and antibodies using xenogenic PAP in the case study with rats where it stimulates autoimmune prostatitis (p.10 col.2 paragraphs 0087-0091).

Regarding the claims Hwang teaches vaccine construct comprising an avipox virus (Fowlpox virus) vector and encoding and expressing a prostrate specific polypetide (see entire article; abstract; p.473, col.1-2 bridging p.474; Table 1). Hwang further teaches that the fowlpox virus vector does not exhibit pathogenic replication indicating it does not productively infect the targeted mammalian subject (human, rodent etc.; see p.473; col.1, Table 2). Hwang further teaches advantages of using a xenogenic form of a prostate specific polypeptide in generating antigen specific CTL and antibodies using xenogenic PAP in a case study with rats where it stimulates autoimmune prostatitis (p.472, col.1; (p.474, col.1). Hwang still further teaches genetic vaccine constructs additionally using co-expression of immunomodulating (immunostimulatory) protein such as IL-2 with the target prostrate tumor specific antigen improved the immunotherapeutic effect of poxvirus (p.475. col.2, paragraphs 3-6 bridging p.476, see p.476, co.1, 2nd paragraph). Hwang still further teaches identification and molecular cloning of various prostrate-cancer associated antigens including prostatic acid phosphatase (PAP, PSA etc) that can be targeted as vaccine. see p.476, co.1, 2nd paragraph.

Thus it would have been obvious for one of ordinary skill in the art to substitute the coding sequences of the generic antigen in the genetic vaccine construct of Leong with McNeel's coding sequences for a xenogenic prostate specific antigen use it as an efficient vaccine for treating a prostrate tumor in a subject as taught in Hwang reference. One of ordinary skill in the art would have been motivated to make and use vaccine construct of fowlpox virus vector with a dual expression of a targeted antigen (PAP) and a immunomodulatory polypeptide (a cytokine) as it would enhances the safety and potency of the vaccine. One of ordinary skill in the art would have reasonable expectation of

success making using vaccine construct in a Fowlpox virus vector expressing a xenogenic prostrate specific antigen and a cytokine gene because the art teaches that it is routine to use a xenogenic antigen to avoid immune tolerance observed with autoantigens and further art teaches that it is routine to use vaccine constructs that co-express certain immunomdoulatroy cytokines that effectively act as adjuvants, enhancing the immune response. Thus, the claimed invention was *prima facie.*

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5-10, 12-16, and 18-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 recites prostatic acid phosphatase or "a derivative… thereof." The claim is unclear for its metes and bounds. To wit, how can any derivative of PAP, which could be even a single amino acid (or less) provide a PAP specific antigenic determinants?

Claims 5-10, 12-16, and 18-19 are rejected for depending from a rejected base claim(s).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 5-10, 12-16, and 18-19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey

to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims broadly require vaccine vectors with “any derivative or any analogue thereof of PAP antigen” and in further limitation require “recombination with any “fowl virus” vector.

The specification, only discloses vaccine vector for only prostatic acid and does not describe vectors for any derivative of PAP or any analogue of PAP and the specification does not describe or define what is meant by a broad term "fowl virus".

Hence, because only embodiment is taught, the Artisan would not have understood Applicant to have been in possession of the genera claimed at the time of invention. One embodiment is not supportive of broad genera claimed.

Conclusion:

No claim allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner *Kelaginamane Hiriyanna Ph.D.,* whose telephone number is **(571) 272-3307**. The examiner can normally be reached Monday through Thursday from 9 AM-7PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *Joseph Woitach Ph.D.,* may be reached at **(571) 272-0739.** The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). When calling please have your application serial number or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. For all other customer support, please call the USPTO call center (UCC) at (800) 786-9199.

/ROBERT M KELLY/
Primary Examiner, Art Unit 1633